

USSN 10/016,821

Response to Office Action dated June 7, 2005

Atty. Docket 3267/FLK (032878-00052)

1. CLAIMS

1. (Currently amended) A tablet for oral administration, which disintegrates in the oral cavity within 60 seconds, consisting essentially of (i) a therapeutically effective amount of an active ingredient, (ii) ~~an effective amount of~~ spray-dried mannitol as a primary disintegrant, of which at least 80% has an average particle size over 100 μ m, (iii) ~~an effective amount of~~ crospovidone as a secondary disintegrant, the components (ii) and (iii) being present in amounts sufficient to cause disintegration of the tablet in the oral cavity within 60 seconds, and (iv) one or more pharmaceutically acceptable excipients selected from the group consisting of an organic acid, effervescent agent, sweetening agent, lubricant, diluent, and flavor in amounts not preventing the tablet from disintegrating in the oral cavity within 60 seconds, the tablet containing no microcrystalline cellulose, not leaving significant amounts of water-insoluble residues, and having a hardness sufficient to be not friable during handling or shipment.
2. (Original) The tablet of claim 1, wherein the contents of the spray-dried mannitol and the crospovidone are in the ranges of 30 to 95% and 1 to 10% by weight, respectively, based on total weight of the tablet.
3. (Original) The tablet of claim 1, wherein the active ingredient is selected from the group consisting of acetaminophen, domperidone, famotidine, meclizine hydrochloride, scopolamine hydrobromide, ondansetron HCl, cisapride, granisetron, sildenafil, loratadine and amlodipine.
4. (Currently amended) A process for the preparation of a tablet for oral administration which disintegrates in the oral cavity within 60 seconds, comprising direct-compressing a mixture consisting essentially of (i) a therapeutically effective amount of an active ingredient, (ii) spray-dried mannitol, (iii) crospovidone, the components (ii) and (iii) being present in amounts sufficient to cause disintegration of the tablet within 60 seconds, and (iv) one or more pharmaceutically acceptable water soluble excipients other than microcrystalline cellulose, selected from the group

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consisting of an organic acid, effervescent agent, sweetening agent, lubricant, diluent, and flavor, in amounts not preventing the tablet from disintegrating in the oral cavity within 60 seconds, the tablet not leaving significant amounts of water-insoluble residues, and having a hardness sufficient to be not friable during handling or shipment.

5. (New) The tablet of claim 1 where the organic acid is selected from the group consisting of citric acid, tartaric acid, fumaric acid, and malic acid.
6. (New) The tablet of claim 1 where the effervescent agent is selected from the group consisting of calcium carbonate, sodium bicarbonate and potassium bicarbonate.
7. (New) The tablet of claim 1 where the organic acid and effervescent agent are present in an amount ranging from 1 to 5 wt% based on the total weight of the tablet, respectively.
8. (New) The tablet of claim 1 where the sweetening agent is selected from the group consisting of aspartam, saccharin, ammonium glycyrrhizinate, xylitol, sorbitol and sucrose
9. (New) The tablet of claim 1 where the lubricant is selected from the group consisting of colloidal silicon dioxide, magnesium stearate and magnesium trisilicate.
10. (New) The process of claim 4 where the organic acid is selected from the group consisting of citric acid, tartaric acid, fumaric acid, and malic acid.
11. (New) The process of claim 4 where the effervescent agent is selected from the group consisting of calcium carbonate, sodium bicarbonate and potassium bicarbonate.

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12. (New) The process of claim 4 where the organic acid and effervescent agent are present in an amount ranging from 1 to 5 wt% based on the total weight of the tablet, respectively.
13. (New) The process of claim 4 where the sweetening agent is selected from the group consisting of aspartam, saccharin, ammonium glycyrrhizinate, xylitol, sorbitol and sucrose.
14. (New) The process of claim 4 where the lubricant is selected from the group consisting of colloidal silicon dioxide, magnesium stearate and magnesium trisilicate.
15. (New) The process of claim 4, wherein the contents of the spray-dried mannitol and the crospovidone are in the ranges of 30 to 95% and 1 to 10% by weight, respectively, based on total weight of the tablet.
16. (New) The process of claim 4, wherein the active ingredient is selected from the group consisting of acetaminophen, domperidone, famotidine, meclizine hydrochloride, scopolamine hydrobromide, ondansetron HCl, cisapride, granisetron, sildenafil, loratadine and amlodipine.